# Privacy & Security Workgroup
## Draft Transcript
## February 19, 2010

## Presentation

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Good afternoon and welcome, everybody, to the Privacy & Security Policy Workgroup Meeting. This is a meeting being conducted in public, and there will be an opportunity at the close of the meeting for the public to make comments. Just a reminder for workgroup members to please identify yourselves when speaking. Let me do a quick roll call before we start the meeting. Deven McGraw?

**Deven McGraw - Center for Democracy & Technology – Director**
Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Rachel Block? I think Rachel is finishing up her panel, I believe, right?

**Deven McGraw - Center for Democracy & Technology – Director**
Yes.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Latanya Sweeney? Gayle Harrell?

**Gayle Harrell – Florida – Former State Legislator**
Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Paul Tang couldn't make it today. Mike Klag? Judy Faulkner?

**Judy Faulkner – Epic Systems – Founder**
Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
John Blair?

**John Blair – Tacanic IPA – President & CEO**
Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Paul Egerman? Dixie Baker.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
I'm here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Paul Uhrig? Dave Wanser?

**Dave Wanser – NDIIC – Executive Director**
Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Kathleen Conner?

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Laurel Stein?  Terri Shaw?  Don Houston couldn't make it either.  Joyce DuBow?

**Joyce DuBow – AARP Public Policy Institute – Associate Director**
Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Justine Handelman?

**Justine Handelman –BCBS – Executive Director Legislative & Regulatory Policy**
On.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Connie Delaney?  Marianna Bledsoe?

**Marianna Bledsoe – NIH – Deputy Associate Director**
Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Peter Basch?  Sue McAndrew?  Joy Pritts?

**Joy Pritts – ONC – Chief Privacy Officer**
Here.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
And Alison Rein and Melissa Goldstein?

**Jodi Daniel – ONC – Director Office of Policy & Research**
They're going to join later for the second half of the conference.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Thank you.  Deven, I'll turn it over to you.

**Deven McGraw - Center for Democracy & Technology – Director**
Okay.  Terrific.  The first item on our agenda, actually I'm going to defer to Jodi to introduce the new chief privacy officer for ONC.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Sure.  Thank you, Deven.  This week, we're fortunate to have Joy Pritts, formally of Georgetown, come and join us as the new chief privacy officer.  We were required by the HITECH statute to hire a chief, to create the position of a chief privacy officer within a year of the passage of ARRA, and we welcome and

are thrilled to have Joy onboard to help us working through some of these challenging privacy and security issues.  And so I've asked her to join this call and to get acquainted with the conversations, the work, and the members of this group.  I don't know, Joy, if you wanted to say anything at all.

**Joy Pritts – ONC – Chief Privacy Officer**
I'm glad to be here and … all the good things about ….

**Deven McGraw - Center for Democracy & Technology – Director**
Great.  Thanks.  We have a heavy breather, which usually is someone with either a cell phone or using a handheld without realizing that we can hear breathing, so please try to hold the phone a little bit away from your mouth or mute if you're not talking.  That would be helpful.  Thanks, Joy.  We're glad to have you onboard, and really glad to have you here on our call, and hopefully in the many to come.

All right.  Moving on, basically we have a couple of things to accomplish today, the first being to do a little aftermath discussion of the Health IT Policy Committee, which was yesterday.  And the second item on the agenda is to look at a much more specific work plan for really what is almost the next, the remainder of calendar year 2010.  It's much more specific than what we had circulated previously.  I think, ideally, we want to get some discussion around this and then bless it, and move forward on it.  And, as noted in the work plan and as we've talked about in the past, one of the first meaty issues, if not the meaty issue that we'll be taking up next is the issue of consumer preferences, sometimes referred to as consent, sometimes referred to as opt in or opt out.

With that, let's start with a discussion of the Health IT Policy Committing meeting, again, which was yesterday.  We circulated all the slides to you all, and the good news is that the policy committee endorsed the recommendations that we made in the document, but there were a couple of questions that came up that, for those of you who weren't present or on the call, I wanted to make you aware of and get some feedback on because we can actually incorporate some of that feedback into a transmittal letter, which will memorialize the recommendations that we made in a letter that will go to Dr. Blumenthal.

Again, good news that the recommendations were adopted.  I think it's a credit to the workgroup and the hard work that we've put in to get them out there.  But the one question that did come up, you'll recall that one of the recommendations that we made was that an eligible provider or a hospital would not be a meaningful user if they were fined for a HIPAA violation at a significant level.  And on the civil side, that willful neglect, which is the highest level of civil violation that's available under HIPAA, were for a criminal violation where the violation is what they call enterprise liability.  The entity itself is criminally liable versus the actions of one rogue employee.

Tony Trenkle from CMS had asked the question of, well, what if the – sorry.  Let me just take a step back.  What we said was you would not be a meaningful user if you were fined for one of these significant HIPAA violations in the year that the violation occurred, which might mean that you might end up having to repay a payment that you initially got on meaningful use if the appeals process, for example, didn't wind itself out until maybe a year or two after the investigation started.  We got confirmation from Tony that CMS had the recoupment authority.  But his question was what if the violations in fact span multiple years, which has actually been the case for some of the HIPAA security rule violations that CMS had investigated when CMS had the authority to enforce the security rule, which was the case until very recently.

Then the other question, because I think these questions are actually closely related, which came from Dr. Blumenthal is, because this kind of disqualification for a meaningful use payment is triggered only when a fine is imposed versus when there's a monetary settlement where there's no finding of guilt, does

that create a greater incentive for entities to settle?  My response to that, you know, we really hadn't talked about that much in our workgroup, but my response to that was that I thought that if an entity was in fact being formally investigated for a willful neglect or criminal violation, that they probably already had a strong incentive to settle.  And in fact that that was certainly what we had seen with respect to these federal enforcement actions where there were monetary settlements involved.  You know, the entities were facing the possibility of some significant civil penalties, and settled to avoid dragging that out.

But the question remains, does this add additional incentive for an entity to settle?  I think it's unavoidable to draw the conclusion that it probably would.  But I'm not sure whether it's that much greater than the incentives that already exist to avoid a public relations disaster of being found to have willfully neglected our nation's privacy laws or to have criminally violated them.  I think it's an open question.  I'll pause right there and make sure that I framed that right for those who were actually there, and get some feedback on how to answer the question.

**Dave Wanser – NDIIC – Executive Director**
This is Dave Wanser.  I think your suggestion about or your response to Dr. Blumenthal is a good way to frame it, and I just don't think there's going to be a whole lot of these, and we're spending a lot of time on something that rarely will occur.

**Deven McGraw - Center for Democracy & Technology – Director**
Right.

**Dave Wanser – NDIIC – Executive Director**
I think, at this point, it's in a good place.

**Deven McGraw - Center for Democracy & Technology – Director**
Thanks, Dave.

**Gayle Harrell – Florida – Former State Legislator**
This is Gayle.  When I look at the whole issue, it becomes really not so much one of monetary penalties or money for a hospital or an entity.  It becomes more of a PR nightmare.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes.

**Gayle Harrell – Florida – Former State Legislator**
And I think the incentive there is to settle, and most entities, I believe, have done that in the past.  I don't know.  There have not been any of these major fines with adjudication of guilt, you know, administered have there?

**W**
No, there haven't been any.

**Gayle Harrell – Florida – Former State Legislator**
You know, so it then becomes a moot question.

**W**
Right.

**Gayle Harrell – Florida – Former State Legislator**

However, from….

**W**
Sorry.  There haven't been any on the civil side….

**Gayle Harrell – Florida – Former State Legislator**
Not on the civil side.  There have been on the criminal side?

**Deven McGraw - Center for Democracy & Technology – Director**
For individuals though.

**W**
For individuals.

**Deven McGraw - Center for Democracy & Technology – Director**
And they've gone to jail, I think.

**Gayle Harrell – Florida – Former State Legislator**
You know, I don't know on the criminal side if you have an option, if there is that much option of settling.  If the prosecutor is determined to go forward, and is not willing to negotiate a plea, you really don't have an option.

**W**
No, you don't.

**Deven McGraw - Center for Democracy & Technology – Director**
You're right.  You're right.

**Gayle Harrell – Florida – Former State Legislator**
You know, so I don't know that the option is really there on the criminal side.  It's really what we're looking at is the fine on the liability side.

**Deven McGraw - Center for Democracy & Technology – Director**
Right.

**Gayle Harrell – Florida – Former State Legislator**
So it hasn't happened in the past.  I doubt, given the financial incentives on the amount of money at risk if you have this, it won't help.  That being said, you have to look at, from the public perception point of view, if indeed this has never happened, and we're setting such a high standard, are we really protecting the public?  You know, so does that make you want to rethink the standard?

**Deven McGraw - Center for Democracy & Technology – Director**
Oh, how high the standard is?

**Gayle Harrell – Florida – Former State Legislator**
How high the standard is that we have set.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes.  I mean, I think that's a good question, and that was actually a question that Christine Bechtel from the policy committee said.  You know, this is a really high bar for disqualifying an entity for meaningful

use.  Do we want something lower than that?  We did talk a little bit about that in the workgroup, and folks were much more comfortable with not barring providers from getting their meaningful use payments until they had sort of gone through the process and then proven to be guilty in some way, and that the lesser civil violations of reasonable cause or did not know of the violation, it seemed unfair, I think, to a number of people to provide such a harsh penalty.

**W**
Deven, I don't….

**Deven McGraw - Center for Democracy & Technology – Director**
But that doesn't preclude.  You know, this is about what we, as a workgroup, can come to concensus on that we would recommend to CMS.  In an open comment period, there's certainly room for people who are looking for something, for a lower bar, and would urge one on CMS to write that in.  But we – I would prefer, for as long as we can, to have our recommendations be concensus based, where we can get them that way.

Let me get to – let me just clarify for Tony's question then when you've got, again, one of these significant HIPAA violations where there is either willful neglect on the civil side, or a criminal violation that extends over more than one year.  Are we comfortable with saying that they would be disqualified from the meaningful use payment in any year where that violation was found to have occurred, again, as long as it preceded to where a fine was levied?

**W**
I think that's a very consistent interpretation of what our intent was.

**W**
I would agree with that.

**M**
Yes, I agree with that.

**Deven McGraw - Center for Democracy & Technology – Director**
Okay.  All right.

**Joy Pritts – ONC – Chief Privacy Officer**
Deven, this is Joy.  I'd like to go back and ask a question, a follow-up question to a point that Gayle rose, which is, although you don't have a settlement in criminal law, you do have something that's kind of similar, which is, isn't a plea of nolo contendere, in which you accept some sort of fine, but you don't admit guilt?

**Deven McGraw - Center for Democracy & Technology – Director**
I hadn't really thought about that.  I was never a criminal lawyer.  Well, I think, consistent with our previous recommendation, you know, we're looking for people to have been found guilty, to have an offense, but in a criminal context.  You know, on the one hand, if prosecutors bring charges, I think a lot of people think that there's likely some validity to it.  On the other hand, there are some very aggressive prosecutors out there that could be a concern.

I don't know.  What do folks think about that?  I'm inclined to say that the most consistent application of where we've been at the workgroup is to say that you need to be found guilty of what you're accused of versus getting out of it through a nolo plea.

**Gayle Harrell – Florida – Former State Legislator**
This is Gayle again.  I believe the nolo plea has to be accepted by the prosecutor.

**Joy Pritts – ONC – Chief Privacy Officer**
Yes.

**Gayle Harrell – Florida – Former State Legislator**
You could plea that, but it doesn't mean that that's going to be the adjudication.

**Deven McGraw - Center for Democracy & Technology – Director**
Right.

**Paul Egerman – eScription – CEO**
Hello, Deven.  This is Paul Egerman.  I'm a little bit late.  I apologize.

**Deven McGraw - Center for Democracy & Technology – Director**
That's okay.  Good to have you.

**W**
Did you say that there was an implicit acknowledgement of the violation with the nolo plea or not?  Do you escape acknowledgement of the violation?  Is that what you said?

**Deven McGraw - Center for Democracy & Technology – Director**
I think sometimes the terms of the plea agreement are no admission of guilt.  It's a good question, but maybe we can think about how to address it….  I mean….

**W**
We're talking about something that's a very small … event … whether it's worth us….

**W**
I wouldn't spend much time on it.  I wouldn't spend any significant amount of time on it, but it might be good to have in the back of your head if anybody asks.

**Deven McGraw - Center for Democracy & Technology – Director**
Okay.  Yes.  Let's not dive into that deep of a level unless we're asked to, would be my suggestion.

**M**
Agreed.

**Deven McGraw - Center for Democracy & Technology – Director**
Okay.  All right.  Well that, I think we made a real good impression with our first set of significant recommendations that we're quite serious about what we're doing here, not that we necessarily needed to convince folks, but I think we came out strong, and the bar has been set high for future work.

On that note, let's move to a discussion of the draft work plan that Rachel and I worked with ONC staff to put before you.  Clearly, between January and February, we got done what we aimed to get done, and now we're looking at sort of the next set of priorities that will take us through the next several months.  What we're proposing here is to tracks.  Phase one of consumer preferences or consent or opt in or opt out, and what I'm calling security priorities.

Partly, we came up with this idea because, one, we really do want to start tackling the consent issue, and it's going to take us some time and a lot of discussion as a workgroup, and some digging in, and even, at least on some level, some public hearings to handle this issue appropriately. On the other hand, I think, based on some of the discussions we had in the workgroup, there are still some security policies and standards that need to be out there sooner rather than later.

We uncovered a couple of these in some of our workgroup discussions, but there could be more. And that if we expect for state HIEs, which just recently got announced for funding with respect to the work that the NHIN workgroup is doing with their investigating some basic policies for connections through the NHIN, which have security implications. Couple that with a sense, even from our own Dixie Baker, who we've got on the line, that there's some more work to do that needs some immediate attention if we expect certified EHR technology to have sort of the full complement of what is really needed on the security side in stage one of meaningful use that we ought to try to be tracking those two things at once. Here is essentially how I propose to do it.

We will have a – I'd like to see if there's some interest in creating a subgroup of members who would develop some recommendations for us on the security side, and so that work could be going on simultaneous with the other work that we're doing on consent, but would allow us to essentially try to handle two things at once. We wouldn't be permanently saying to this subgroup that they had our full workgroup authority, but instead asking them to come up with a set of recommendations, which then we would consider in the full workgroup, and then pass on to the policy committee.

I've already sort of spoken to two folks on our workgroup who I consider to have a lot of security expertise: Kathleen Connor from Microsoft, and Dixie Baker, who is the cochair of the privacy and security workgroup of standards. But others who would want to be involved are certainly welcome to be. I'm just trying to figure out a way to really light a fire under this process and allow us to get two really important priorities done in a shorter period of time. And I want to know what you all think about that.

**Gayle Harrell – Florida – Former State Legislator**
This is Gayle. I really think that's essential, and to look specifically at security because that becomes a very technical issue, and there are a lot of things on a very technical level that need to be discussed, if we can break that out. And it needs to happen very quickly. I know here in Florida, we have a lot of HIEs standing up, and the issue is out there. It needs … the time essence is very important.

**Paul Egerman – eScription – CEO**
Yes. Deven, this is Paul Egerman. I agree. The subgroup is a good way to handle it, especially with Dixie being involved. Also, we need to make sure we use better coordination with the standards committee. As I said, it sounds right.

**Gayle Harrell – Florida – Former State Legislator**
It should be more than just two people though.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. I agree. Are there other folks? I will definitely be involved, but are there other folks, not that security is my area of expertise, but I want to be able to be feeding in what's going on and at least monitoring it, even if it's not my substantive area. But are there others in the workgroup who are interested? It is asking a bit more work of the folks who are sort of on this track because, you know, to be quite frank, the expectation is that the subgroup will be doing more, while also still participating in the consent discussion, which is going to go on in our regular calls. So it's a lot to ask.

The other thing I want to throw on the table is whether we could tap into perhaps some more of the folks from the standards group to be part of this, and so we wouldn't be formally adding them to our whole workgroup, but asking them to help with the subgroup work of teeing up some security policy recommendations that then might, in fact, need further work from standards, but at least we'll be doing it in a coordinated way.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
I can tell you, I'm going to tell you two things. I know, Deven, that you understand this, but for the rest of them. The standards work that we've done so far was constrained by having to be derived from the HITSP body of work and having to be within the policy that's laid out within HIPAA. Even within the standards workgroup of the privacy and security workgroup, we really felt like our hands were tied, and some of the people – we actually looked at all of the HIPAA addressable implementation specifications, you know, and identified those that we thought really needed to be made equivalent to required if you had an EHR, and so we've done that work. But it couldn't go anywhere because it wasn't derived from HITSP. We've done some of the discussions, and we have some work the group could start with.

**Jodi Daniel – ONC – Director Office of Policy & Research**
This is Jodi Daniel. One … response to Deven's question about bringing in folks from the other committee, I just want to make sure. I mean, you know, I think it's really important that we have Dixie as sort of a bridge between the two, but I want to make sure that the conversations in this workgroup are really the policy direction, and that we don't get into the weeds of standards and technical specifications and things like that. That's my one concern. Although I'm perfectly comfortable with, and I think it might be a good idea to bring in some more expertise with respect to security policy to make sure that the workgroup is better informed about possible directions that you guys might want to recommend that the standards committee work on.

I guess my inclination, although I'd be very interested in other folks' thoughts, and particularly Dixie's thoughts on this, but that I would try not to make the group sort of get too, you know, kind of overlapping. But make sure that we do have, if we need to bring in more security expertise to help us form that discussion, I think that would be perfectly appropriate.

**Paul Egerman – eScription – CEO**
I think that comment is excellent because, I mean, I'm looking at the agenda. For example, it raises an issue about secure e-mail. But the way I interpret your comment would mean that this group could say, well, secure e-mail needs to be addressed. We won't say too much beyond that. That's the standards committee to figure out.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Yes, I couldn't agree with you guys – I'm sorry. Jodi, you're right on the money. I think that where the standards committee was constrained because of a lack of policy that would justify a standard, that's really where this committee really needs to step in and say, okay. We believe that this should be a policy for, like the NHIN. This should be a policy for the exchange across the NHIN. Once that policy is recommended, then the standards committee is the one to step forward and recommend the standard.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
I have a slightly different point of view on this, and how we use the secure e-mails is an example. There are some policy issues that have somewhat of a technical flavor, but if they're not put forward by this group, then it leaves a gap for directions on the standards side. Specifically, ideas about what kinds of secure transport you need when you have multiple nodes or IP service providers in between, whether you

need authentication on the e-mail, so there are a number of policy issues that if we don't go a little further down than saying secure e-mail is a good thing, we will have left a lot of discussion that will have policy implications….

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
That's where the standards committee should push back.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
Well, but also….

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
…established a policy, and then the security committee should recommend the standards. Where there are issues, then the standards committee should be pushing back and say there are technical issues here.

**W**
But it seems as though, like you two might actually be really helpful in thinking through the level of policy direction that would help drive the technical folks to think through the issues related to the technology and the standards. Do you think that we need; do you think that you can represent … issues, or do you think we need more technical expertise on a subgroup to bring that out?

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
This is Kathleen again. I've listened to the calls, and they've been great discussions, and the standards committee seems to recognize the points at which the technology choices start making policy decisions. The people that are really attune to that might be useful to have some of them participate because the gray area is hard to navigate. Dixie, what do you think?

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. I think there's a clear understanding and concensus that what we want to deal with in our committee is the policy piece of this. But also, a recognition that sometimes the line between when it's policy and when it's dictating a technical standard is sometimes a bit of a slippery one, and so I think we have enough, unless I'm mishearing things from the group here.

Number one, it sounds like people are very much onboard with tracking this, which is great. Number two, folks want to stick with the important policy issues that need to be defined in order to give the standards committee adequate direction and intension on what needs to be addressed, where there are more specifics that need to be developed, and that's sort of beyond the scope of what the policy committee ought to be dealing with, but understanding that sometimes there's, you know, there are policy implications inherent in the technological choices, and that we ought to do as much as we can to resolve those policy pieces and turn over and ask standards to address those pieces that are really with respect to the technical specifications. Does that make sense?

And if there are people who either are on the standards now, or who are sort of more known in the technical community as sort of having that sort of policy antenna, that those might be the right people to ask, of course, without making the group too big. Does that make sense?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
I have a suggestion maybe. Kathleen said she's been calling in on our meetings, so she knows how often I push back. Some of our people are chomping at the bit to get into the policy arena, quite frankly. What about if we had a, one, joint meeting of the two workgroups?

**Deven McGraw - Center for Democracy & Technology – Director**
Well, so here's the thing. It's not a bad idea, and I'd actually like to do that when we have some things to put on the table. But what I'm worried about is, number one, I wanted to track this in a way so that security could be working on a parallel track, so I wouldn't envision if we were to have a joint meeting, that happening until we're fairly close to being ready to recommend some stuff.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Well, I was thinking even to sort out who does what and areas that the standards workgroup members already feel should be addressed. It might give them an opportunity to say policy committee, here's something I would really like for you to tackle.

**Paul Egerman – eScription – CEO**
This is Paul Egerman, Deven. I also have a question about this, reading the very first bullet. The focus on security priorities that were not part of the initial certification, and it goes on to say, but should be part of the certified EHR or, I guess, the HER….

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. It's supposed to be EHR. My computer fixes that automatically.

**Paul Egerman – eScription – CEO**
Yes, they all do. But it should be part in stage one. Isn't it too late at this point?

**Deven McGraw - Center for Democracy & Technology – Director**
Yes, you're right.

**Paul Egerman – eScription – CEO**
I didn't understand that.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes, that was il-phrased. We can't do much more. We can't do any more in the IFR than I think we've already done. But I do think there's a recognition that there are some things that got left out that are important for technology to include as early as possible. And that's why, essentially, I'm suggesting this dual track, because otherwise we could take up some of this longer-term security stuff on the policy end, you know, later, and not have to do it in two tracks. But you're right, that's an important correction. Our ability to influence the IFR, we said what we said, and that's likely passed.

**Paul Egerman – eScription – CEO**
Yes. And so this is really talking about stage two stuff.

**Deven McGraw - Center for Democracy & Technology – Director**
Well, yes, and, well, you know. Technically, I think that's right, and it's unfortunately. But here's the, yes, stage two for the certification program, but if you look at what NHIN is putting on the table, the decisions that they have to make, which includes secure transport, there are a whole lot of decisions that, while our ability to apply them to the systems at the edge may not be as strong as getting it into the IFR, from a timeliness perspective, they've got to be made now.

**Paul Egerman – eScription – CEO**
I'm trying to absorb all this discussion about high level versus detail and looking beyond this committee, but realizing that we're really talking about what's going to happen in stage two. Maybe the focus for this

group is, say, by the April meeting to simply come up with a work plan or a list of topics that are security topics that need to be addressed. We want to make sure we avoid creating this subgroup that exists forever.

**Deven McGraw - Center for Democracy & Technology – Director**
Right. I understand.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Yes….

**Paul Egerman – eScription – CEO**
…security … what we're going to try to do is, by some date in April, have a list of security topics that need to be addressed or priorities that we want the workgroup to assign to the standards committee.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
That's a good idea, and I could even ask the standards workgroup for what they would like me to suggest be on that list.

**Paul Egerman – eScription – CEO**
Yes.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
You know, that could be a nice bridge. Yes.

**Gayle Harrell – Florida – Former State Legislator**
Deven, this is Gayle again. I think we really have to look at the NHIN in this whole context because, to me, that is really the gap right now. You know, stage two is down the road a little bit, but right now we need to really look at the security issues that are coming up immediately as the HIN group makes their – the NHIN makes their recommendations. And you have these local HIEs standing up.

**Paul Egerman – eScription – CEO**
Gayle, this is Paul. That's true, although there are other security issues in addition to that that need to be….

**Gayle Harrell – Florida – Former State Legislator**
Yes, I absolutely agree. But that's why I think--

**Paul Egerman – eScription – CEO**
Use the example of e-mail, yes.

**Gayle Harrell – Florida – Former State Legislator**
--it's paramount that we move forward fairly rapidly.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. I mean, I like the idea of using the subgroup as sort of task one being list of topics for us to consider for stage two. I think that's right. But I think if that's the only thing they're doing, there'll be some decisions made on security policy with respect to the NHIN that we will have sort of lost our opportunity to weigh in on, and I guess I'm focusing on this secure e-mail piece of it because unless I wasn't understanding the presentation, and I've been sitting in on those workgroups, they've envisioned much of

the exchange occurring by e-mail for less mature exchange marketplaces. And that's, you know, if we don't have a requirement to make it secure, it seems like a gaping hole.

I recognize that that's both an EHR systems at the edge problem, as well as the interconnecting transport mechanisms that are going to be part of the NHIN. And it may be that NHIN is the place where those questions get resolved. But I would want us to, in some way, try to be a part of that.

**Gayle Harrell – Florida – Former State Legislator**
Well, I truly believe we need to be a part of that.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
Yes. This is Kathleen. I don't think their governance extends much beyond the group, the small group that's involved with that, does it? You have to be invited to get into that group and be a contractor with one of the entities, unless that's changed.

**Deven McGraw - Center for Democracy & Technology – Director**
No, that's different. Yes, it is changed. They're trying to set national baseline policy that isn't about connecting to the existing NHIN.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
Right. I apologize. I was thinking of the NHIN CONNECT group.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes, not NHIN CONNECT, which is a related, but….

**Rachel Block – New York eHealth Collaborative – Executive Director**
I'm sorry. It's Rachel. I just wanted to let you know I joined … minutes ago.

**Deven McGraw - Center for Democracy & Technology – Director**
Thank you.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
I do think Gayle has a good point though. If you start looking at NHIN, and then look at not only security issues relating to the exchanges themselves, but information, security policy within an organization that could impact the security across the NHIN, so not just take on internal enterprise security, but there are some attributes of internal policy that affect the security of the NHIN itself. You know, one obvious one is how individuals are authenticated within an organization. Even though that's internal, if you go past the identity across an NHIN exchange, it has an impact on the whole NHIN. So the idea of looking at the problem from the perspective of NHIN, I think, is a really good one.

**Deven McGraw - Center for Democracy & Technology – Director**
Let me restate what I think is an immediate task of this subgroup, which would be, one, to look at those NHIN issues, as Dixie so well articulated it, including those that are internal that have an impact on NHIN security policy, and also coming up with a list of those issues that we need to consider for stage two. Does that make sense?

**Paul Egerman – eScription – CEO**
Yes.

**Deven McGraw - Center for Democracy & Technology – Director**

All right.

**John Blair – Tacanic IPA – President & CEO**
Wait one second. Deven, this is John Blair. So in that first piece, with the NHIN, that's with the existing NHIN, right? You're talking CONNECT?

**Deven McGraw - Center for Democracy & Technology – Director**
No, I'm not talking CONNECT.

**John Blair – Tacanic IPA – President & CEO**
Okay. Then I'm fine.

**Deven McGraw - Center for Democracy & Technology – Director**
Okay. We're not trying to rewire what's going on in CONNECT.

**John Blair – Tacanic IPA – President & CEO**
Okay. I thought Dixie meant that though.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
No, I sure didn't.

**John Blair – Tacanic IPA – President & CEO**
Okay. All right.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
No, no.

**Gayle Harrell – Florida – Former State Legislator**
Nor did Gayle.

**John Blair – Tacanic IPA – President & CEO**
Okay.

**Deven McGraw - Center for Democracy & Technology – Director**
Good clarification, John. Thank you. We don't want to make anybody--panic anybody.

**John Blair – Tacanic IPA – President & CEO**
All right.

**Deven McGraw - Center for Democracy & Technology – Director**
That's good, I think. I think that'll help us make some progress faster and allow us to cover more things at once. The main track, track one is the discussion of consumer preferences for health information at what we've termed as a course level, which is sort of more of opt in or opt out. Either you're in or you're out, without thinking about sort of the granular aspects of this. We have – we're not ignoring the granular aspects of this because we understand that, with respect to state law, for example, consents are very granular, and often are about specific types of data.

We know that there's a desire on the part of, and with respect to the Federal Substance Abuse regulations, those are also very granular with respect to data sharing, so we're not avoiding those. But at least in our preliminary discussions with staff, the thought is to try to get us to some concensus on the

bigger picture issue of should there be some policy at the federal level of being able to opt in or opt out of electronic health information exchange. And, if so, what would that look like? Then sort of level setting that within our own group because we really, we kind of danced around this topic a little bit, but I haven't let you get into it because we've had other things on our agenda, and so we don't even really know where people are, at least initially on how they feel about that topic.

Then moving to what I think is a much more complicated discussion when you get to, okay, if we are going to give people choices here, at what level of granularity? That's consistent, actually, with the way that the national committee on vital and health statistics rolled out its recommendations, which apply with respect to participation in the NHIN, which is to think about it first at that sort of nongranular course general level, and then to really drill down on specific data types. So I want to get feedback on that as sort of an overall plan for moving forward.

**Joyce DuBow – AARP Public Policy Institute – Associate Director**
Deven, can I just ask a question about course?

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. Go ahead, Joyce. It's a tough term.

**Joyce DuBow – AARP Public Policy Institute – Associate Director**
Sort of general principles that would guide what happens to the granular information?

**Deven McGraw - Center for Democracy & Technology – Director**
That might be another way of looking at it. You know, I think, in our discussions, in preparing this work plan, we thought about it in terms of opt in or opt out at a whole cloth level. You either are required to opt in to having your records be part of health information exchange, or you get to not participate in this as a consumer without thinking about sort of at a more granular leve whether you could then layer on top of that, not only can you say it as a whole, but you could say it by provider, this type of provider, that type of provider, or diving down to the data level where, to some extent, we do have some law already on the books.

**Joyce DuBow – AARP Public Policy Institute – Associate Director**
Okay. So … granularity talks about flushing out … implications of each situation.

**Deven McGraw - Center for Democracy & Technology – Director**
I think that's right, but I think, you know, it's again, I think, if you dump into the granular discussions without at least having the level setting discussion at the front end about content in general, I think it's a little bit harder to get into the granularity. But I'm open to discussion about that.

**Jodi Daniel – ONC – Director Office of Policy & Research**
This is Jodi Daniel. I think, also, just to support what Deven is saying, there's a lot that we still need to bring out in discussion and learn from as far as the technical capabilities for data segmentation, if that's something that the group is interested in focusing on, and sort of the workflow issues. You know, all of these very interesting issues that come up when you start talking about what we're calling granular consumer preferences. We're trying to deal with kind of … start with the broad concept, which is really where at least a lot of the HIEs have focused. The ones that have come up with policies on this that are either operational or close to being operational. To see if we can get the group and hopefully get the group to a point where there's some concensus at that level.

Then once we have sort of that baseline, then kind of delve further in, and if that changes where we were at the beginning, that's fine. But we're trying to sort of do this in a methodical way based on what we know, what folks are doing, what the capabilities are today, and then working into some of what I would call the more challenging issues when you get to granular consumer preferences, sensitive data. It raises a whole lot more policy issues, technical issues, etc.

**John Blair – Tacanic IPA – President & CEO**
There's another aspect to the landscape, and that is consent for the data upload or putting the data in the system versus consent for access to it.

**Deven McGraw - Center for Democracy & Technology – Director**
Right.

**Jodi Daniel – ONC – Director Office of Policy & Research**
And I think that you would probably get into that conversation. Deven, tell me, or Rachel, if you have a different view that that would still probably be under track one. That would still be course, course level for, and if the group wants to divide it up that way, I think that would be fine. But still looking at sort of the all in, all out, or all in for particular purpose, I mean, all in, you know, just to upload it or all in to access it or all out. So I think we were still – I think that that probably could be folded into the first level conversation.

**John Blair – Tacanic IPA – President & CEO**
I'm not sure it does. It's different than all in and all out.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. I think what Jodi….

**Jodi Daniel – ONC – Director Office of Policy & Research**
For the consent … okay….

**Deven McGraw - Center for Democracy & Technology – Director**
Right, but that may be where thinking of all in or all out in two directions.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Right.

**Deven McGraw - Center for Democracy & Technology – Director**
I hope we're not losing folks.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Be a little more specific.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. John, are you referring to the policy that New York has adopted for its HIE?

**John Blair – Tacanic IPA – President & CEO**
Yes. So, I mean, if you look at some of the Massachusetts examples versus New York, in New York, the data goes in. There's not, you can't stop … but then it is, you get access to the providers to look at that data. Versus Massachusetts where it's assumed that the provider that cares for you as access to it, but

you consent to the information going in.  I mean, really two different models with very different implications.

**Deven McGraw - Center for Democracy & Technology – Director**
The way you described it, John, makes it sound to me like maybe different ways of framing an opt in, actually, in the case of both states.  That you could … as different ways of framing an opt out.  But … all in or all out, although I thought, in New York, it was also by provider type.

**W**
Can I suggest that we … because we have some time set aside at the second half of the agenda to talk, you know, kind of start talking about this issue, that we just try to get some concensus around the work plan, or do we need to actually…?

**Deven McGraw - Center for Democracy & Technology – Director**
But I think that's the discussion we're having is sort of what's meant.  If we're going to separate out a course versus granular discussion, what do we mean by course?

**John Blair – Tacanic IPA – President & CEO**
Yes, and also, this is as big as course versus granular.  It's two completely different ways to approach it.

**Deven McGraw - Center for Democracy & Technology – Director**
Right.

**Paul Egerman – eScription – CEO**
Yes, and this is Paul….

**Deven McGraw - Center for Democracy & Technology – Director**
Let me make a suggestion that I think what we meant in particular by granular, and of course I'm saying we, and there's a number of us on the call that were part of pulling this together, but I don't … so Jodi, Joy, Rachel, can correct me if I'm wrong.  But I think when we get to the more granular piece, we would think of that granularity in terms of types of data or data sets, and then think of the course as either sort of either all in or all out, different ways to operationalize that, and maybe even extending so far that that choice being by the provider, like this doctor and not that doctor.

Or, if we're not quite ready to make that decision yet, we can, at least on this call, commit to trying to do this in two phases, and not be quite so regimented about what we decide is course versus what we leave for a later, granular discussion.  I'm trying to preserve the notion of getting at this in kind of two phases because I fear that if we don't try to break it up with some flexibility about where we draw those boundaries, we'll have trouble having a focused discussion.

**Paul Egerman – eScription – CEO**
Yes.  Deven, this is Paul.  I understand your issue.  I understand the two phases.  But I guess I'm not understanding why the granularity comes second and not first.  I know there's one vendor, who I think you know, you understand, who … you can't do it on a granular basis.  It's really got to be all in or all out.

**Deven McGraw - Center for Democracy & Technology – Director**
I think there are a number of people who think that way, but that's why – but I also think that there are folks who don't think there ought to be, that there needs to be an all in or all out choice.  I don't know that we have any of them in our workgroup because we've never sort of, again, had this discussion.  Getting at this sort of threshold of whether we ought to be giving people some choice with respect to whether or

not their data is part of this enterprise as a threshold matter, versus then diving into, well, under what terms and conditions.

**Paul Egerman – eScription – CEO**
Yes.  The question I'm asking is, should we do it the other way?  Really understand that issue, and understand that we're doing all data, or we're going to do granular, and maybe that helps … then how we do the patient option, because maybe if it's only, this is all in or all out, and that's all we decide we're going to do, because that makes you look differently than if there's a whole spectrum of choices.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
This is Kathleen.  I wanted to echo what John said, and going to agree with Deven because I think we can look at the opt in, opt out for collection and for access to discern some of the salient issues that will be important if we go to the granular level.  So it doesn't preclude that.  It doesn't keep us from making the decision that there will be no granularity.  But we do need to really understand the implications of having those choices made at collection versus….

**Paul Egerman – eScription – CEO**
Okay.

**John Blair – Tacanic IPA – President & CEO**
Yes, I agree.  I think you've got to go the collection versus access first because we my decide that you need consent on collection and access, or one of the other, but you've got to go through that exercise before you get to the granular piece.

**M**
Okay.

**W**
I would agree.

**Judy Faulkner – Epic Systems – Founder**
This is Judy.  I'm okay with that too.  But I think that a provider should be on the granular list, not on the course list.

**Deven McGraw - Center for Democracy & Technology – Director**
Okay.

**John Blair – Tacanic IPA – President & CEO**
Yes, I agree with that.  I hadn't thought about granular with providers.  I thought more about the data, but I agree with that.

**Deven McGraw - Center for Democracy & Technology – Director**
Okay.

**Joy Pritts – ONC – Chief Privacy Officer**
Deven, this is Joy.  I have a question.  When the group is approaching this, you had mentioned NCVHS … recommendations within the context of the NHIN.  What particular context is the group focusing on here that NHIN … advice to state health information exchange, exchanges or other regional HIOs?

**Deven McGraw - Center for Democracy & Technology – Director**

That's a good question, Joy, and it's not one where we've made decisions, and I think that would be part of the workgroup discussion, which is where that choice applies.

**Joy Pritts – ONC – Chief Privacy Officer**
Okay.

**Sue McAndrew – HITSP – Deputy Director**
This is Sue. I mean, if it helps, in terms of the NCVHS recommendations, they were basically at a place that said it would be up to the provider to decide whether or not he was going to move to an electronic health record system. But before that system then began exchanging data with other systems is where there might be the need for this particular course or total opt in or opt out on the part of the individual would first come into play. So it wasn't that the individual would be given the choice about whether or not the provider could maintain an electronic health record for him. The choice would come into play at the point about whether or not that individual felt comfortable in having that information shared electronically with another.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
This is Kathleen. I think there's a slight different between collecting information in a local EHR for use by that provider versus collection in the sense that it's available for exchange.

**M**
That's right. Yes.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
The latter one that we were kind of looking at, not this first time, local collection, but I could be wrong on that. I had one other thing I wanted to say was in the list of granular considerations, could we add purpose of use because there's all the treatment, payment, operations, which have more flavors now, etc. And also some conditions around sharing, like the one condition is any further disclosure would require additional consent. That's an example, so those two, what I'd call, parameters for granular consent.

**John Blair – Tacanic IPA – President & CEO**
Yes. I get a little nervous in putting sharing between systems and making that synonymous with uploading or data into an exchange for a community type of record.

**Deven McGraw - Center for Democracy & Technology – Director**
I think all of these are issues that need further deliberation. In fact, Sue, when I read those NCVHS letters, to me they speak specifically only to the NHIN and participation in that, which, of course, depending on how you define it, that sort of sets the parameters for what's meant by exchange. Unfortunately, John Houston, our person from NCVHS, couldn't be with us on this call. But we'll have him on subsequent calls, and we have a suggested list of things that I think we'll need to read and think about and consider because this road has, you know, people have thought about this previously. And we ought to take all of that into consideration as we talk about it.

I'm hesitant to try to narrow the confines more than what I think have been very good suggestions that we've gotten on the call for trying to distinguish between sort of the early side of the conversation, which is that the course level, which includes collection versus access versus something more granular down the road, which includes granularity at the provider level, and types of data, whether it be sensitive, based on purpose, etc. There's sort of probably a lot of different ways you could slice it.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**

Deven, this is Dixie again.  The other thing that should be addressed, even at that top level, is the information access is where the information doesn't really flow anyplace.  Information views, in other words.

**Deven McGraw - Center for Democracy & Technology – Director**
Views or the difference between use versus--?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
No.  Some of the HIEs are implementing the ability to access information without the information actually flowing, the … actually flowing, sort of like go to MyPC kind of thing or Citrix where you can actually see something, but nothing gets down – no data actually gets downloaded to your computer.

**Deven McGraw - Center for Democracy & Technology – Director**
Right.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
That's still access.

**M**
Yes, all of….

**W**
Very much so.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes.

**M**
Yes.

**M**
Yes.

**Deven McGraw - Center for Democracy & Technology – Director**
I have been hearing about those models.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Yes.  That's becoming more and more popular.  And it's good, from a privacy perspective, because your data aren't flowing all over the place.  From policy, we need to consider it.

**Paul Egerman – eScription – CEO**
Yes, this is Paul Egerman….

**W**
Well, the other thing that….

**Gayle Harrell – Florida – Former State Legislator**
…access to the data, whether you download it or you just view it, you have knowledge of the data.

**Deven McGraw - Center for Democracy & Technology – Director**

Yes.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Yes.

**Paul Egerman – eScription – CEO**
This is Paul Egerman. That's right.  It's information exchange versus data exchange.

**W**
Yes, I mean….

**Paul Egerman – eScription – CEO**
Either way, you do have access….

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Yes, that's exactly right.

**Paul Egerman – eScription – CEO**
If you read it, you can write it down, so you still have … same issues.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Exactly.  Yes.

**W**
Well, you not only can write it down, you legally have to if you make any decision based on what you saw.

**Deven McGraw - Center for Democracy & Technology – Director**
You've got to incorporate it into your record in some way that that means you have to type it in separately.

**W**
Correct.

**Gayle Harrell – Florida – Former State Legislator**
Right.  You're legally liable for that information once you've viewed it.

**M**
Right.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
It really comes into play with insurance companies deciding whether they're going to cover something. They may just look at information and decide, yes, that's fine, without downloading your entire record.

**W**
It also comes into play if there's a lawsuit, and people want to know why you made the decision you made.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Yes.

**W**

You need to have a record of that, which is why most organizations do want the information there for that legal liability.

**Deven McGraw - Center for Democracy & Technology – Director**
Right.

**W**
But isn't this a different use from when clinicians are using it for treatment? Wouldn't they…?

**W**
For treatment, yes.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. I don't want to dive down too far into this one particular model because I think we could probably easily spend the next hour talking about, but it is one that I've heard of that sort of where rather than having the data flowing across networks, you get a view of it. But then I think there are some other considerations that come into play. All of that, I think, we ought to explore.

We've got, quite frankly, we've given ourselves a pretty tight timeframe for trying to get some of this done, which is yet another reason to try to divide it up a little bit to at least get some preliminary recommendations out there for the policy committee to chew on sooner rather than later because they, as a whole, will have input on it. And putting it forth in that additional public forum can help stimulate feedback from the public as well.

One of the things that we wanted to – all right, so let me just – let's just make sure we're okay with the rest of the work plan that we've got here. A two-track plan for the sort of next few months, consent at the course level, as we've discussed it today, some security issues that are related to NHIN, as well as a list for stage two, kind of going on simultaneously, continuing that consumer preferences discussion at a more granular into the early part of the summer. Then what we've got teed up for the summer really is a discussion of secondary uses of data related to health information exchanges. Remind me what the acronym of HISP is for. This is something that's arising out of the NHIN discussions: Health Information Service Providers?

**John Blair – Tacanic IPA – President & CEO**
Yes.

**Deven McGraw - Center for Democracy & Technology – Director**
Thank you, John. The second, the NHIN again, and PHRs we've included on here, although you'll see we've put a particularized discussion of PHRs and privacy in September through November, and I think this was a bit of a tough choice between which of these you prioritize. But to me, the discussions about sort of patient choice inevitably rise. The concurrent question arises, which is, well, consent to what? What types of data sharing are we talking about? If it's just data that's being shared for treatment or are there sort of other issues for which we might be using these health information exchange networks that we're creating that need to be addressed.

It seemed to me that if we're going to tackle consent first, that always is a conversation that ought to be in the context of data uses, what are appropriate data uses, and for which maybe we'd have consent on one, but not on others. At any rate, we've got secondary uses teed up immediately afterward. PHRs are important as well, but by the time September rolls around, we'll have, I think, the study of, you know, the

recommendations or the study on policies, privacy and security policies for PHRs that the federal government is required to do.

ONC has long been at work on a model, privacy notice for PHRs, and that will be presumably farther down in the pipeline. And, at any rate, that's the reason for the ordering there. Then we listed a few others that we have put on our list that obviously we don't sunset after 2010, so we haven't forgotten about them, but we didn't slate them specifically for consideration in 2010. Of course, we'd love to get feedback on all of this from you all.

**Marianna Bledsoe – NIH – Deputy Associate Director**
Hello. This is Marianna Bledsoe from NIH, and I had a question about the secondary use discussion because, particularly, I think, if we start talking about purpose of use in the granular consumer preferences discussion that we may get into some discussions about other uses, and so I don't know how easy it's going to be to parse these out so cleanly.

**Deven McGraw - Center for Democracy & Technology – Director**
I couldn't agree with you more, Marianna. I suspect that some of what we resolve on the consent question will get into purposes, whether they be primary or secondary, and how you draw those lines. But I still think that to the extent that we're looking at sort of using these networks for purposes beyond sharing for treatment, such as for payment and for research, and that we ought to spend some dedicated time talking about that. But I think I fully acknowledge, you know, it's always a challenge….

I fully acknowledge that these things are overlapping, and it's always a challenge to try to keep the group focused, but acknowledging the interplay really among all of these issues. And so I'll – and you guys can push back and remind me that, at some point, there may be a point at which there are questions that we cannot resolve without diving more deeply into some of these other interrelated.

**Marianna Bledsoe – NIH – Deputy Associate Director**
Right, and as we make recommendations in these phases, I think it's important to think about sort of the downstream implications, to make sure that as we make recommendations in one phase, that that's not going to have some sort of downstream effect in some of these issues that we'll get to into in the later phases.

**Deven McGraw - Center for Democracy & Technology – Director**
Right.

**Judy Faulkner – Epic Systems – Founder**
This is Judy, and I want to amend something I said earlier about providers under the course versus the granular.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes.

**Judy Faulkner – Epic Systems – Founder**
I think providers, as the healthcare system, should be under – the problem is the multiple definitions of the word provider.

**Deven McGraw - Center for Democracy & Technology – Director**
Right.

**Judy Faulkner – Epic Systems – Founder**
And you had mentioned both in one of the write-ups.  But as a healthcare system, I think it should be under course.  As an individual provider, it should be under granular.

**Deven McGraw - Center for Democracy & Technology – Director**
Okay.

**Gayle Harrell – Florida – Former State Legislator**
Why do you say that, Judy?  This is Gayle.

**Judy Faulkner – Epic Systems – Founder**
Because I think, when you get into the discussion of course, it will become inevitable to have to consider course as University of Pennsylvania as the whole thing, versus Betty Ford Clinic as the whole thing, that it comes into the course definition.  But when you get down to Dr. Smith or Dr. Jones, it comes to the fine definition.

**Gayle Harrell – Florida – Former State Legislator**
You're talking mostly about vertically integrated systems versus…?

**Judy Faulkner – Epic Systems – Founder**
Exactly.

**Gayle Harrell – Florida – Former State Legislator**
…kind of systems?

**Judy Faulkner – Epic Systems – Founder**
Exactly.

**Paul Egerman – eScription – CEO**
This is Paul Egerman.  I partly agree with you, Judy, but I would say it's not just vertically integrated.  I mean, let's say you have a four-person pediatric group.  I mean, they may be organized in such a way that all four pediatricians see a patient, and so they have one medical record … course is at an entity level.

**Judy Faulkner – Epic Systems – Founder**
Yes.  Course set at the entity level, I agree with because, well, actually, it's course at a level where they have a separate EMR.

**Paul Egerman – eScription – CEO**
That's correct.  That's correct, which is presumably an entity, but may not be, I suppose.

**Judy Faulkner – Epic Systems – Founder**
Yes, well, the entity could just be Dr. Smith in that case.

**Paul Egerman – eScription – CEO**
That's correct.

**Judy Faulkner – Epic Systems – Founder**
But then you can trust more whether all that information can go back and forth, or be segregated, whereas … entity that shares information, cutting it up is much harder to do.

**Paul Egerman – eScription – CEO**
That's correct. Or to put it differently, the issue of sharing information within the walls of an entity or a medical group, an IDN is different than sharing it from one institution to another.

**Judy Faulkner – Epic Systems – Founder**
Yes.

**Paul Egerman – eScription – CEO**
And so—

**Judy Faulkner – Epic Systems – Founder**
So I think it's going to touch … the person from NIH was saying, things do get mixed up.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes.

**W**
Yes.

**Judy Faulkner – Epic Systems – Founder**
We are going to get mixed up inevitably.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. I mean, I think that's right. While we're going to, I think, continue to try to take this on in a couple of phases, I think we have to acknowledge that there's a contextual aspect to all of this that will, you know, we have to loosen up some of those boundaries a bit in order to be able to reach concensus on this. But we'll have to see where those are, so some of this we'll try to leave a little fluid.

**Judy Faulkner – Epic Systems – Founder**
Sounds good.

**Deven McGraw - Center for Democracy & Technology – Director**
Okay.

**Gayle Harrell – Florida – Former State Legislator**
Yes.

**Deven McGraw - Center for Democracy & Technology – Director**
That sounds great.

**Gayle Harrell – Florida – Former State Legislator**
Quite a discussion, Deven. Good girl.

**Deven McGraw - Center for Democracy & Technology – Director**
So one of the things that we thought we might do is to go ahead and start looking and get a sneak peek really at this white paper that the Office of the National Coordinator had commissioned on this consumer preferences issue. And so Jodi, can I turn it over to you? How do you want to handle that?

**Jodi Daniel – ONC – Director Office of Policy & Research**

Sure.  Let me just ask.  Are Melissa Goldstein or Alison Rein on the line?

**Melissa Goldstein – Dept. of Health Policy – Associate Research Professor**
This is Melissa.  I'm here.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
As am I.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Great.  Do we have the – hold on.  I'm not online.  Do we now have the PowerPoint up?

**Deven McGraw - Center for Democracy & Technology – Director**
Not yet.  Alison, can we have the PowerPoint, the ones with the – there you go.  Excellent.  They're up.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Thank you.  Great.  Now I'm on. We knew that ONC, we knew that this was a big issue for us to take on, the … consumer consent options for health information exchange.  And there's been lots of discussion over many years about these issues.  And there are lots of different factors that go into thinking through the policy issues, and what the right or how to think through the discussion and kind of get into all of the things that you all have just been starting to raise.

And so what we wanted to do was develop a white paper that just puts all of these issues in one place, and uses some examples that we've seen from the states to give some perspective.  It looks at these issues from the provider perspective, the patient perspective, from the vendor perspective, and the HIE perspective.  It thinks through different; it looks at other different kinds of lenses like how does the extent of consumer choice affect consumer actions.  How do different choices affect consumer decisions?  Looking at legal issues, what laws are out there?  Looking at ethical issues, etc.

What we wanted to do was have a white paper that kind of sits all of this in one place, and sort of gets a baseline of different perspectives, different issues, different experiences, all in one place so that we can have a more thoughtful discussion about the policies without trying to get all the issues on the table.  What we did was we engaged GW, and Melissa Goldstein is on the line as the person who is leading this effort for us from GW to develop a white paper that does just that, that kind of does this level setting and gets all of these issues and ideas in one place so that we can have a good discussion about some of the hard stuff.

And I've asked Melissa and Alison Rein, who is working with her, to join us so that, to the extent that there are questions about what they've done or the way they've thought through this, that they can jump in, or if they have anything to add about what I'm saying and if I'm misrepresenting some of what they have pulled together.  Just so you know, we're going to be doing a series of these white papers.  We started with consumer consent or consumer permissions.  Then we'll next be and started working on a paper related to data segmentation, and then we may have other papers as well that tackle other issues and tee them up for this workgroup and for ONC.

Did I say that well?  Anything to add, Melissa or Alison, that you want to just give context here?

**W**
I think that was great.  Thanks.

**Deven McGraw - Center for Democracy & Technology – Director**

Can I ask a question, Jodi?  This is Deven.  When do we think the actual whole paper will be ready?  Not to put you guys on the spot.

**Jodi Daniel – ONC – Director Office of Policy & Research**
We had that conversation yesterday.  We don't have an exact date, but we're pretty much in the final draft stage, so I would say probably a matter of weeks.  We're kind of in the final home stretch.  I can't give an exact date, but as soon as we have the paper available, we'll make it available to all of you.  And we hope – the goal was to have this paper available to inform these discussions.  So I'm going to present what I have learned and what we've discussed with the GW folks about what they're putting in this white paper, even though we don't have the white paper ready for you all.  But there will be a lot more detail, a lot more insights that you'll see once you get the paper.

Okay.  Can we go to the next slide?  Okay.  So I actually went through some of this.  The paper goals, again, we're trying to identify issues and challenges regarding various consumer consent models for how the challenges are being addressed by active and emerging electronic exchanges, so looking at some of the real world experience people have had with these different consent models that are out there. Looking at the consequences of this for a variety of stakeholders, patients, providers, and others.  And then consider how the impact of these different approaches … because we're not just obviously trying to protect privacy, but the whole point of health information exchange is to try to improve health outcomes. We need to do that in an environment of trust and protection, but we want to also make sure that our health IT and health information exchange efforts are focused on important health goals as well, so looking at how those all fit together.

Next slide, please.  Some of the issues and challenges, and I'm probably preaching to the choir on some of this. You guys, I'm sure, know a lot of this.  But it's obviously balancing many competing and interests of multiple different stakeholders, and trying to think about how we can best – how the different models address those different interests, and coming up with and thinking through the policy recommendations, how we try to create a balance of those interests and not just look at it through one lens.  And that's hard because….

Obtaining and managing consent in an appropriate … efficient manner, so a lot of approaches that one might look at, some are easier to implement.  Some are more challenging to implement.  And thinking through how the attaining and the managing of the consent itself affects the policy, affects the approach we're taking, and affects the protection.  So, again … challenge.

Third is insuring that adequate patient and provider participation in the exchange effort.  So again, how you implement the consent model, if you do have a consent model, and how you engage providers and patients has a huge impact on the success of your efforts to promote health information exchange, and so that's another challenge is figuring out how we appropriately, both inform, educate, and engage providers and patients in discussions about health information exchange and about any choices that there are.

We've obviously federal and state laws, which are always a challenge, and the variations that those make coming up with policy in this area very difficult, and then establishing supportive, adequate, protective policy framework.  Obviously, while we're very much focused on the health information exchange and health goal, we want to make sure that we're establishing a supportive and protective policy framework that allows folks to have trust in the exchange efforts that we're trying to promote.

Next slide.  By the way, Melissa or Alison, feel free to jump in if there's more that you think I should say or verification on anything I'm saying based on your work.

The basic model that the GW folks were looking at was a no consent model because, first, let me just say, we asked them to look at the spectrum, so from no consent or no consumer … at all to a fully opt in model where information doesn't flow unless the consumer explicitly … upfront. On the one end of the spectrum, there's no consent. That information is automatically included in health information exchange without any opportunity to opt out. And I'm now looking at this and thinking about the conversation we just had about the including in the health information exchange versus accessing it, and we probably should – this wasn't only focused on information inclusion. But I think this should be brought in to incorporate that discussion.

Opt out, where information is automatically part of the health information exchange, unless an individual opts out of that information to be included. And we talked about this. There are two variations on this theme: either opt out completely, so it's all or nothing. You're either in or out. Or an opt out with exceptions where, and this sort of gets into a little bit more of the granularity conversation. Then opt in where information is not automatically included. That there must be consumer permission before the information is included. Again, with the variation of this being either a full opt in, it's either all or nothing. Once you say yes, it all goes. Or whether or not there should be some restrictions on that opt in.

**Paul Egerman – eScription – CEO**
Jodi, can you explain the exception to restrictions, or is that something that you'll come to later?

**Jodi Daniel – ONC – Director Office of Policy & Research**
No, we can talk about that. Again, here, Melissa and Alison, feel free to jump in. But, so for instance, if there are state laws that specifically say that you must particularly consent to your mental health data or your HIV data being disclosed, you may need a separate. You may not be able to do a blanket opt in. There might need to be an opt in with some restrictions, and then a separate opt in for particular types of data. So it kind of gets to the sort of most in, but there might be some exceptions to that rule, or most out, but there might be some exceptions to that rule.

**Paul Egerman – eScription – CEO**
But the exceptions are based on law, as opposed to patient choice.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Not necessarily. I don't think that we've explicitly limited it to that in the discussion. Alison or Melissa?

**Alison Rein – NCL – Assistant Director Food & Health Policy**
We have not. The use of the terminology, I think, you know, essentially you can think of them as being the same thing. But the language that we saw in references to the definitions, so each of these three is actually in the paper there are five different models that we lay out, and each of them is at least a lengthy paragraph. Hopefully that will help, but in looking at the references for coming up with these definitions, that was the language that was associated most frequently with each of these options. So we were mostly trying to be consistent with the language of opt out versus opt in.

**Jodi Daniel – ONC – Director Office of Policy & Research**
But it's to explicitly limited to law. It also could have been based on consumer preferences.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Exactly. There is nothing else to read into that.

**Deven McGraw - Center for Democracy & Technology – Director**
In other words, people granting them over and above what the law may require potentially.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Yes, so I don't want anybody to read in a legal, a necessarily legal interpretation into those terms.
Melissa, is that – do you want to add anything to that?

**Melissa Goldstein – Dept. of Health Policy – Associate Research Professor**
No. I think that's fair. I think, basically we were trying to be broad enough to include what people
considered to be opt in with restrictions, that it either could be legally required, or not necessarily, or the
system or entity itself could allow it, even though, like Deven just said, over and above what the law
requires. It could be any of it, actually, and we have, in the paper, which we do expect to be out probably
within a month, we go through many examples of different entities we spoke with and different state ones
or other ones, and how they approach these issues. The examples are actually, they help illustrate what
we're talking about in a more abstract sense.

**Judy Faulkner – Epic Systems – Founder**
This is Judy. On the previous slide, the key issues, challenges slide, another area that I think is a key
issue is what can be done accurately by the technology that exists in order for whatever is chosen to be
done in a way that is accurate so that patients can trust it.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Right, and that is absolutely something that we have built in, and I guess that would sort of be captured
under the second bullet on key issues and challenges. We have a section that deals with sort of the
logistic and technical, etc. But per Jodi's earlier reference to a subsequent paper that deals more with
segmentation, I think that we decided to hold off on a lot of the detail technical discussion until we got
further into it since this was intended to be more of a high level effort.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Does that help?

**Judy Faulkner – Epic Systems – Founder**
I think the second bullet, the opinion of managing … appropriate, effective, and efficient manner, that
one?

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Mm-hmm.

**Judy Faulkner – Epic Systems – Founder**
Yes. I guess it's a little hard for me to see that it also includes what can be done.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Those ideas are really woven throughout the paper. I guess these slides are sort of an initial … framing
effort.

**Jodi Daniel – ONC – Director Office of Policy & Research**
I think, Judy, that's a very valid point, and there is some discretion in the paper about the technical
capabilities and looking at it from a technical perspective as well. But you're right. That's not clear from
this, but….

**Judy Faulkner – Epic Systems – Founder**
Yes.

**Jodi Daniel – ONC – Director Office of Policy & Research**
I'm sorry?

**Judy Faulkner – Epic Systems – Founder**
It's certainly a key challenge.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Yes.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Yes, I agree. And I think it is captured in the paper, but we'll take a look at that as well and make sure that that is represented.

**Kathleen Connor – Microsoft Health Solutions – Principal Program Manager**
Jodi, this is Kathleen. I had a question about the paper. Did it differentiate the opt in/opt out by collection versus access?

**Alison Rein – NCL – Assistant Director Food & Health Policy**
The definitions do not, but the examples do, so there's discussion that gets to that, ut the five basic consent model definitions don't necessarily differentiate that. We could obviously, you know, if it's, I mean, based on further conversations with the folks at ONC, if there's a desire to build that more strongly into the definition section, I think we could go back and look at it. Our original thinking was that we were trying to just give a bare bones definition of consent, you know, regardless of what the contract was, and so that starts to get more into the context. And we tried, in the paper, to sort of have a definition section that was a little cleaner, and then get into the messy stuff later.

**Jodi Daniel – ONC – Director Office of Policy & Research**
But I think the point of, and I do think, again, and I realize we're sort of saying, you know, trust us … we're just trying to tee up these issues, but I think we'll take a look at that based on the conversation we just had with the workgroup about there may be very different issues with respect to consent and having information being available and collected and uploaded versus access to that information. That might be something we can look at, and make sure it is addressed, whether it's in the definition section or otherwise, but it's a valid point. I think … like Alison was saying in the discussion and in the examples that are being used. But … identify that a little bit….

**W**
This is…. I just wanted to note that that has been an outstanding area of concern in other national HIE efforts is that distinction there between the consent to collect and consent to access.

**Jodi Daniel – ONC – Director Office of Policy & Research**
And I think, you know, just because we always do things in a thoughtful way, or if they just tend to work out in a thoughtful way, but … helpful that we're kind of presenting some of the basic concepts here because some of this discussion is helping. Will probably help us think through on our final read through of this and making sure that we've gotten some of the questions and the issues that are being raised by this workgroup represented in this white paper, so this is all very good feedback.

Next slide. To talk about granularity, we had, again, some conversations earlier in this call on this. These are just, again, these folks are going to be working on a separate paper focused specifically on data segmentation. But just at a high level, looking at the different types of granularity options that they've

identified and that we've seen are listed here. So the first is by data type, and this is usually what people say when they're talking about data segmentation. There are various examples of this, but it's something that both we need to move forward because of HITECH legislation, and because the capabilities, you know, trying to think through what capabilities … in the future, and because of some of the specific legal requirements tied to particular types of data.

**Paul Egerman – eScription – CEO**
…examples, what about, for example … pediatric progress notes? Is that a data type, or is that a combination of data type and provider?

**Jodi Daniel – ONC – Director Office of Policy & Research**
Yes. I think, combination of both.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
A combination of both. I think, actually, by data type, it wasn't necessarily intended to be, I mean, it could be all labs, all meds, all progress notes, or it could be something more specific like all medications related to a specific condition. So we didn't try and define what would constitute the data type. I think you're right. It's possible. I mean, it's a challenge because what we've tried to do is present cleanly delineated things, while acknowledging that there's nothing clean and delineated about this space. But it is quite likely that you would have multiple permutations and layers.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Right.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
And I think that that is certainly that we have tried to address, but obviously, based on conversations and whatever conversations you all have had, if we need to do more on that, you know, we can have that conversation.

Joyce B.
Alison, this is Joyce. I think, at least you have to acknowledge that it's hard to do that. it's hard to parse cleanly because people are going to look for policies that are cleanly delineated, unless you tell them that that's very difficult to do.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Right, and that is absolutely the case.

**Melissa Goldstein – Dept. of Health Policy – Associate Research Professor**
Hello. This is Melissa. We have stated that … clear.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
I did want to repeat the critical … also that you see here is that what a lot of exchanges are doing right now, or what we see some of them doing is that they'll just exclude sources of … sensitive information. So if it's a substance abuse facility, they just won't allow. They just don't include any information from that facility in that exchange because folks haven't quite figured out how to segment by data type once that data is in an exchange.

What folks have done, at this point, what we've seen is that they just exclude the sources of the data. I remember when we did katrinahealth.org when we were working on trying to get prescribing information for victims of Katrina to make them available in clinics where folks who were … New Orleans were being

treated, or other hurricane areas were fleeing.  We tried to help folks to make information and pharmacy information, pharmaceutical information available so that clinicians had some information to help treat patients and get them back on their meds.

What that group who pulled together katrinahealth.org did was, because they didn't know how to deal with sensitive information, because every state law was different, if it was a mental health drug, they just didn't include it, which of course raises some significant policy issues about differential treatment based on condition, and you raised the policy issues about making information available to some folks who really would have gotten a significant benefit from having providers have that information.  We've seen this in some instances where folks didn't know how to grapple with the laws, and have in fact excluded bits of data because of some of the legal requirements.

**Paul Egerman – eScription – CEO**
One sort of partly related question I have, Deven, is … you're using the word "exchange" a lot relating to this issue.  Are we talking about consumer choice relative to exchanges as nouns or as verbs?  In other words, is part of our model still point-to-point access in exchange without an HIE in the middle?

**Deven McGraw - Center for Democracy & Technology – Director**
This piece of paper, I mean, Jodi can explain what the paper covers.  My own view is that, in terms of our workgroup deliberations, is that that's part of what we ought to – that ought to be part of what we consider in terms of our recommendations.  We have consent policy and what does it apply to.

**Jodi Daniel – ONC – Director Office of Policy & Research**
In the paper, and again, Alison and Melissa, correct me if you need to.  They talk about exchange more broadly, but then where they're talking about specific examples, and it's focused on a noun, the exchange, they make that clear.  So it doesn't hint that they're not taking policy positions in this paper … little bit less of a problem, but they're sort of exchange … discussion is about exchange as sort of a broader, in a broader context with the focus on what's happening in health information exchanges, as a noun, in particular instances.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Yes, I mean, I think we were trying to be agnostic as to the environment, and I think that is only because, had we not done that, we could have ended up writing 50 different papers describing the exact name issue, but applied to 50 different exchange environments.  And so what we tried to do was do a high level overview of sort of all, you know, the range of issues and, as Jodi said, try and be specific as to examples of where we were talking about a noun versus a verb.  There's a short section that tries to just provide a brief overview of the exchange landscape, but then we have not taken the rest of the paper and put it in the context of each of the possible permutations within that landscape.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
This is Dixie Baker.  I have a question.  Are the consents for the exchange, are those collected at the same time as patients provide consent to their providers?  I mean, provider….

**Rachel Block – New York eHealth Collaborative – Executive Director**
Can be, but not always.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Beg your pardon.

**Rachel Block – New York eHealth Collaborative – Executive Director**

It can be, but it isn't always that way.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Sometimes there are like two layers of consent?

**Rachel Block – New York eHealth Collaborative – Executive Director**
Well, also, with some of our RHIOs—I'm sorry, this is Rachel—what some of our RHIOs are doing is basically providing a Web consent service that could be done at any time.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
I see. Okay.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Yes, there are multiple examples, and some health information organizations felt really strongly that it needed to be through the provider and not the point of care, and others took very different approaches.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Thank you.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Okay, so there's data type. We already talked a little bit about provider type, either by provider organization or by individual provider. And we've, again, by experience, seen some examples of segmenting or separating out data based on provider organization, but very few, if any, examples by individual provider, again, because of the … back to our earlier discussion. By time range, you know, so kind of taking out historical data, Melissa or Alison, do you want to talk any more about that?

**Alison Rein – NCL – Assistant Director Food & Health Policy**
Only if people have questions about what it means.

**Deven McGraw - Center for Democracy & Technology – Director**
Yes. I just wanted to—Jodi, this is Deven—I just want to give you a nod that it's close to 3:40.

**Jodi Daniel – ONC – Director Office of Policy & Research**
Okay. Let's try to go through this quickly, and then maybe we'll take some questions at the end. Then by purpose, again, many are just leveraging exchange for information for treatment purposes, some for public health … but … also these granularity of choice based on the purpose or some type of exchange, so limited to certain purposes.

Next slide. Possible approaches for insuring adequate participation, this is one of the challenges upfront. One thing that is explored and discussed in the paper is about both insuring adequate participation by patient and providers, and some of the discussion here is about those two. Again, how do you actively engage patients in the development and oversight of the exchange, and how educating them about the benefits of exchange, as well as their options? Whether or not you provide multiple access points if you have an opt in model, again, to help increase participation in the health information exchanges. That's the goal. Versus the establishment of opt out or no consent model.

With respect to providers, a lot of – trying to get adequate participation, a lot of it comes down to minimizing administrative burden, so the question is how you obtain consent, whether you have the providers obtaining consent, which may be more effective, but providers more administrative burden. And are there ways of making it simpler on providers if you are getting the consent at the provider level?

But then that's … access to useful information for the provider so that they see a benefit to participating … participating in exchange. And the big issue providers have in participating in health information exchange is some liability and other concerns about their participation in general.

Next slide. I'm not going to get into detail on this. We can, if we need to, when we have more robust discussions on this. But clearly the federal and state laws pose kind of … all of the thinking and the policy on the consumer choice options. We obviously have the HIPAA privacy rules, but then there's also the Genetic Information on Discrimination Act, which sets particular rules on genetic information, and the confidentiality of … patient records, which sets a higher bar for medical records by certain alcohol and drug abuse facilities, treatment facilities.

Then, of course, state laws, which vary widely based on consent cultures. There are many states that have very liberal laws about health information sharing and others that require consent in most cases for information to be shared. And states are sort of moving at different rates to address some of these legal barriers to exchange based on either how sophisticated their exchange efforts are, as well as the cultures of the states or their legislative sessions, etc. There's sort of a lot that underlies and sorts of challenges in thinking through the best consumer choice models for health information exchange. We're looking at this from the nationwide perspective.

Next slide. I'm going to try not to go into too much detail because we're running low on time, but one of the things the paper tries to do is balance … multiple stakeholders, so looking at patients, what the patients want, what providers want, what payers want, and what information exchanges, if we're talking about exchange as a noun, what they need or want, and setting up the exchange. And again, trying to balance the interests of these and thinking through the policies so we end up with policies where we have significant participation, both the patients and providers, as well as exchanges that are working efficiently and effectively.

**Deven McGraw - Center for Democracy & Technology – Director**
That's it. That's the last slide.

**Jodi Daniel – ONC – Director Office of Policy & Research**
This was really just an overview of sort of some of the scope of what's going to be in the white paper, and there's going to be a lot more detail, a lot of examples of what currently is being done in different health information exchange efforts, and so hopefully we'll get that out to you in a few weeks, and that will help inform the discussions, but I want to at least take, since we're kind of far along in this process, I want to at least give you a flavor of what will be addressed in that, and how it might, so that folks can think about how that might help inform and shape the discussions of this workgroup.

**Marianna Bledsoe – NIH – Deputy Associate Director**
Jodi, this is Marianna. To what extent is research uses considered in this paper?

**Jodi Daniel – ONC – Director Office of Policy & Research**
Yes, again, there's some discussion about the segmenting by the purpose, but the paper, and again, Alison and Melissa, feel free to jump in. It doesn't go into detail about particular types of—

**Alison Rein – NCL – Assistant Director Food & Health Policy**
We actually have a section called the impact, and it basically tries to address the potential impact of various consent models, choices for broader societal goals, and among those are reduction in health disparities, you know, the ability to conduct research, etc. But as Jodi points out, we sort of cover that

with broad brush strokes, and it's not really any level of significant detail as to sort of what the implications might be, and talk about the numerous different types of research and what the data needs might be, etc.

**Marianna Bledsoe – NIH – Deputy Associate Director**
Right, because there are federal laws, again, that pertain to research uses, so the common rule, for example, that isn't listed on your slide … that's why I asked the question. And I think, as we move forward, to talk about secondary uses, we'll have to probably delve into some of those issues.

**Judy Faulkner – Epic Systems – Founder**
Jodi, this is Judy. Who is an exchange executive?

**Alison Rein – NCL – Assistant Director Food & Health Policy**
That was our attempt at a very generic term of describing somebody who is responsible for a health information organization, and if it's not as formalized as an HIO, then presumably most, well, I don't even want to say most, many exchanges will have to have some sort of formalized agreement structure within the participating organizations, and so it could be that the executives would just be the executives of the participating exchange who have a role in making governance decisions, or it could be in a more formalized HIO, somebody who is actually sort of leading that effort.

**Judy Faulkner – Epic Systems – Founder**
If there's a vendor system that does exchange, then the executives of that EHR would be an exchange executive?

**Alison Rein – NCL – Assistant Director Food & Health Policy**
I don't think that was the – that was not the intention.

**Judy Faulkner – Epic Systems – Founder**
Okay.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
If that's something that we need to more explicitly consider or address, then I'm sure Jodi will….

**Deven McGraw - Center for Democracy & Technology – Director**
Well, you might need to, actually, because certainly some of where the NHIN workgroup recommendations and discussions have been going presume that exchange may be facilitated by a number of different entities, of which vendors are included. You know, but whether that triggers, you know, whether there's some sort of governance structure that needs, you know, some consideration in terms of balancing multiple stakeholder interests, it's kind of hard to tell. I think some of this stuff is just being sketched out. But on the theory that exchange will occur, ideally through, potentially through multiple ways, but I'll leave that for you to discuss among the contracting parties on this paper.

**Judy Faulkner – Epic Systems – Founder**
The reason I ask is because if in fact that does represent someone like me, I would have a different list. And my list would include that there was clarity about what we're supposed to do and clear definitions of, well, and no contradictions that we didn't have situations where we have a legal requirement to be interoperable, but we can't do it because the way it is defined is not possible to do, so you're into a huge contradiction that there was clarity between state laws and federal rules. So again, you weren't stuck into things that were not possible to do both of them from the exchange side of things.

And also, I would want really clear definitions of how to get the information. This is on the technical side. We have now much more of a focus on what to get than we have how to get it. And the definition of rules of the road so that we knew everyone who was, every organization that was participating in this knows the rules of what they're doing. And I think some of that is what you're doing right here, saying what those rules will be legally. But a lot of it I would have under that list of what we want is clarity that what is there doesn't contradict itself, and that….

If that makes sense, but in other words, I keep worrying that it's a deadly embrace between interoperability and some privacy laws that may come out, maybe not through this, but maybe through state laws that in fact it's not possible to do both.

**Paul Egerman – eScription – CEO**
Yes. Those are good comments, Judy. But when I look at this slide, I thought when they said exchange executives, they meant exchange executives of an exchange as a noun, so … somebody like Micky Tripathi as a stakeholder.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
That is definitely what we had in mind.

**Paul Egerman – eScription – CEO**
Yes.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
But we wanted to acknowledge that it could be, you know, it could be that there is a collection of hospitals in a region that have decided to exchange data, and maybe it's the executives of those four or five hospitals that has some sort of governance structure around how they're going to organize … and what rules are going to apply. But it was definitely assumed as being either for an entity or an organization, not necessarily … technology vendor.

**W**
Right.

**Paul Egerman – eScription – CEO**
So the….

**W**
The goal is to….

**Paul Egerman – eScription – CEO**
So the list that Judy just gave represents she's a vender. That's not a stakeholder according to this slide. Is that correct?

**Melissa Goldstein – Dept. of Health Policy – Associate Research Professor**
Our basic goal with the paper was to really analyze the models and to make our analysis applicable to as many different types of exchange that people are engaging in now or might in the future as possible so that the model that we discussed, that people could look at this analysis and think, well, how does that apply to us? How does that apply to what we're doing? While we didn't specifically mention different vendor engagement in exchange, we did mean for it to be large. And I think, when we use the word executive, we probably do mean the Micky Tripathi model.

**Jodi Daniel – ONC – Director Office of Policy & Research**
But I think some of Judy's points are very well taken.

**Paul Egerman – eScription – CEO**
Absolutely.

**Jodi Daniel – ONC – Director Office of Policy & Research**
…want to just … them in, particularly the issue of clarity about rules, which does apply, even if you are talking about the Micky Tripathis of the world, that understanding how their state law interacts with some other states laws interacts with our federal policy and what that translates to for operating an exchange. I think that's absolutely something that would be important, whether it's from Judy's perspective or Micky's perspective.

**W**
Sure. People want an answer.

**Gayle Harrell – Florida – Former State Legislator**
This is Gayle Harrell. I want to add the point that, at times, vendors are carrying on exchange. And it's, in that case, would – I would presume that they would be included if they're enabling exchange between particular providers who use their product.

**Alison Rein – NCL – Assistant Director Food & Health Policy**
I think that the distinction that we were trying to make, at least in my own head, and maybe that's not right, was there's got to be somebody responsible for establishing whatever rules and protocols are going to govern how the entity, whatever it is, is going to treat the exchange of information. And presumably that can't be done simply by a technology. There has to be somebody in charge or a group of people in charge. And so as Melissa pointed out, we weren't trying to point out all of the different types of entities that could be the people in charge so much as point out the range of issues that they would have to consider.

But I think your focus on technology vendors is an interesting one and, quite frankly, it had never occurred to me that you could rely on a technology vendor to make all of the determinations about how an exchange would work, absent any sort of overarching policy structure or governance structure. And so that may be something that we need to discuss and perhaps address further in the paper.

**Paul Egerman – eScription – CEO**
Yes. This is Paul Egerman. If you look at an exchange….

**Deven McGraw - Center for Democracy & Technology – Director**
Paul, I'm afraid you're going to have the last comment before we have to open this up for public comment.

**Paul Egerman – eScription – CEO**
I'm not sure that exchange, even as a noun, is a stakeholder, the same way patients and providers and perhaps payers are. Those are all groups of people who have some interest in making sure the exchange occurs correctly. Whereas, the exchange executives, they are in some sense similar to vendors. Their job is really to service the other stakeholders. That's what they're trying to do.

**W**
Right.

**Paul Egerman – eScription – CEO**
And so, in my mind, they're in a different category.

**W**
It's still people, however.

**Paul Egerman – eScription – CEO**
Absolutely, and nice people, a good sense of humor … wonderful people.

**Deven McGraw - Center for Democracy & Technology – Director**
I'm afraid we've reached – we're close to the end of our time here, and we need to provide some time for public comment. While the folks are doing their magic to open up those lines, I want to thank everybody for a very productive call today. We are, right now our earlier March scheduled call, which I think was originally on March 4th or March 5th, had to be rescheduled, and we haven't done that yet, but we will because I think we've got to have two calls in March in order to really move aggressively on this stuff in the way that we want to. We'll make some revisions to this work plan per our very good discussion today, get it back out to folks, so you've got it. And I'll follow up with our security team of two and ONC staff to talk about how we move forward on that separate track.

**W**
Great.

**Operator**
(Instructions given.)

**Judy Sparrow – Office of the National Coordinator – Executive Director**
…for a comment?

**Operator**
We do not have any public comments at this time.

**Deven McGraw - Center for Democracy & Technology – Director**
There must be. Give it a couple minutes.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Yes.

**Deven McGraw - Center for Democracy & Technology – Director**
Or a minute. We know there was somebody waiting.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Yes.

**Operator**
We have a public comment from Deborah Peel.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Thank you.

**Deven McGraw - Center for Democracy & Technology – Director**
Thank you.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Dr. Peel?

**Operator**
She disconnected.

**Deven McGraw - Center for Democracy & Technology – Director**
Oh, deer.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Let me see if I can e-mail her.

**Deven McGraw - Center for Democracy & Technology – Director**
Give her another minute to come back.  I'm really looking forward to getting this paper, I have to say.

**W**
Yes….

**Deven McGraw - Center for Democracy & Technology – Director**
Hurry up and finish that, you guys.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
While we have everybody on the line, how does March 19th look as a date?  Although our next meeting, call would be on the 25th.

**Operator**
Ms. Sparrow, Deborah Peel is back.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Okay, good.

**Deven McGraw - Center for Democracy & Technology – Director**
Great.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Dr. Peel?

**Deborah Peel – Patient Privacy Rights – Founder & Chair**
Hello.  Sorry, everybody.

**Deven McGraw - Center for Democracy & Technology – Director**
No, that's okay.  Go ahead.

**Deborah Peel – Patient Privacy Rights – Founder & Chair**
This thing is really hard to use.  I had a couple of things to bring up.  In regard to the new ONC paper and the preliminary discussion paper, would it be possible for all of us to get copies of the five definitions of consent models because we may have some comments or some other ideas that the team might want to

consider since they're not all in the paper, I mean, in this handout that was posted today?  That would be one comment.

The second thing is, there's clearly a tremendous need to know what are the existing consent technologies, and I don't know if the team doing the white paper had a formal way of trying to engage the innovative companies that are doing consent technology, but one of the things that our coalition asked Dr. Blumenthal after meeting with him was for a one-day conference on consumers and privacy with a half-day of that to be spent looking at actual demonstrations of consent technologies.  It seems to me, that really fits in with the discussion today and all of the things that are coming up on your agenda.  And so, we would really like to work with you, Deven and Jodi, and try to get that going because it's really critical for people to see the consent technologies that are out there.

And, in addition, not only consent.  There are existing EHRs that allow segmentation of information.  And so, I think there's a disadvantage to having only one EHR voice on the committee because really there are EHRs come in all kinds of flavors with all kinds of, again, possibilities.  And we don't want to build to the, if you will, build a system in a way that blocks out the innovations and the improvements that people want.

And a third comment that I have is, you know, a lot of the information in the paper talks about the balancing of individual rights to privacy and control over personal information with the interest of many others.  And we really think that that's, you know, actually not the right approach to the problem of how are we going to get information.  I'd just like to give you an example from another area, what people are thinking about privacy and personal information in electronic systems.

There was a conference I was at in D.C. not long ago where Blair Leven, who is with the FCC, and has been charged with developing the nation's broadband plan, had this to say about it.  He felt that the way to get the maximum use of individual information and trust in the Internet and electronic systems is for individuals to have control.  And he was not even talking about health information.  The example that he gave was the use of smart grids and the upcoming smart houses where our houses have, you know, every light, every appliance, every room we're in noted and tracked.  And he was very concerned that we won't be able to get the applications to allow individuals to monitor and change their own use of energy unless they're absolutely certain they control the energy.

And so, he is talking about, as the model of broadband and broadband use internationally, needed to be not this kind of paradigm of balancing interests because he rejected that as false.  He says that in fact what privacy and the right of control of personal information is a gating phenomena, meaning, if you don't have it, people will stay off.  And you won't get the data, and that's exactly the problem with opt out systems.  If people are forced to have all of their information in, into a system, without control, then what you'll have is, at the level of the doctor or the beginning, you won't get sensitive information.  You'll just have that information left out.

I just wanted you all to be aware, there really is a context even greater than just healthcare where privacy is so sensitive, and many others are realizing that the way we get the most information is when people trust that it's going to be used in the way that they want.  And so I think we really have to be careful about the interests of supposedly the other stakeholders because, you know, in our view, and in the view of most Americans, the control really belongs in their hands because they are the patients.

Just one other comment, again, about problems with these systems when they're built in the wrong way.  One of the things we're starting to see right now are lawsuits around the country about people that hold data or use it in ways that are unexpected and unacceptable.  For example, in Arizona, the Havasupai Indians sued the state because some blood samples that were given for diabetes research were later used without consent for other kinds of studies on mental illness and things that they didn't like.

And we're seeing this all around the country, and certainly here in Texas, we have 5.4 million blood spots that are about to be destroyed because the state did not know how to provide a consent process. And so we have the loss of all this very invaluable research information because the state did not know that there really exists today great consent technologies that would enable people to consent to research for the use of their spots. And so I think we're at the beginning of the problem that we're going to see when people find out they don't control their information.

And so, again, I would just caution you to try to look forward in not only your work on the committee, but in this white paper to not think only of what we have today because most of the technologies we have today, as you all know, are really quite primitive. And we don't want to be locked into systems that are so primitive, they can't offer what Americans expect and what have been their rights for so long. I guess those are the main points that I wanted to make. And we really look forward to trying to work with you to begin to have some focus on consent. We're thrilled that this is so high on your agenda, and we hope that you'll help us and urge Dr. Blumenthal to put together the kind of conference we need so that we can really see demonstrations of what consent is all about. Thank you so much.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
Thank you.

**Deven McGraw - Center for Democracy & Technology – Director**
Thank you very much, Dr. Peel, Deb. We'll note that all that is very helpful information to have. Appreciate it. Okay, folks. Thank you for hanging in. Stay tuned, and also especially if you get a note from Judy about dates.

**Judy Sparrow – Office of the National Coordinator – Executive Director**
…thank you.

**W**
Thank you.

**W**
Bye.